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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,006	09/16/2003	Claudio Argento	ECV-5662	1753

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EDWARDS LIFESCIENCES CORPORATION
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EXAMINER

BARRETT, THOMAS C

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,006	Applicant(s) ARGENTO, CLAUDIO	
	Examiner Thomas C. Barrett	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed July 7, 2006 have been fully considered but they are not persuasive.

Contrary to the Applicant's argument, the sizer/marker has not already been removed before suturing. In paragraph 98, Schoon et al does not disclose the step of removing the suture template:

"In the preferred embodiment, the sizer/marker posts and scallops are oriented to assure clearance of the coronary ostia. For example, marking at the inflow edge can result in three 120 degree spaced dye marks aligned in a plane slightly below the patient's excised aortic leaflets. Three sutures may then be placed using a vertical interrupted technique such that the distal end of each suture exits from the tissue at each mark. The distal suture ends are then passed through the inflow edge of the valve prosthesis at their corresponding 120 degree spaced markings. The sequence of suture routing, number of sutures, and method of suture placement may be at the discretion of the surgeon."

In other words, the template is properly oriented in the heart, marks are made in the notches of the template, **and then** the sutures are placed.

In addition, the motivation to combine was taken directly from column 21, lines 39-52 of Donlon et al, as noted in the prior action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-13 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Schoon et al. (2003/0078651). Schoon et al. discloses a method of attaching a prosthetic valve at the aorta of a heart (paragraph 0095), said method comprising: placing a suture template (e.g. Fig. 13) having a plurality of notches at a location of the heart that is to receive the prosthetic valve; attaching a plurality of sutures to the location of the heart by placing the plurality of sutures through the plurality of notches of the suture template and through the location of the heart and removing the suture template from the location of the heart; and attaching the plurality of sutures to the prosthetic valve and fixing the prosthetic valve at said location (paragraph 0098).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoon et al. (2003/0078651) as above. While Schoon et al. doesn't disclose cutting the template to remove it, it would be obvious to one of ordinary skill in the art to cut the template if, for example, the template becomes stuck in the heart because it

cannot be left in the heart. Furthermore, regarding claim 17, as noted in MPEP 2144.04 IV C, "selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results." Therefore the suture is attached at the commissure portions inherently before, after or simultaneously with the attachment at the cusps; none of which orders are patentably distinct from other.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoon et al. (2003/0078651) as above in view of Donlon et al. (6,651,671 B1). Schoon et al. discloses a method of attaching a prosthetic valve using a template as above. However Schoon et al. does not disclose using a suture organizer or sliding the valve along the sutures. Donlon et al. teaches a method of implanting a valve comprising the use of a suture organizer (col. 21, lines 39-52) and sliding of the valve down a plurality of 10 sutures (col. 20, line 61- col. 21, line 35), the sutures having a needle at each end, attached to a sewing ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of a method of implanting a valve comprising the use of a suture organizer and sliding of the valve down the sutures, as taught by Donlon et al., to the method as per Schoon et al., in order to keep the sutures orderly and free from tangles (col. 21, lines 39-52).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

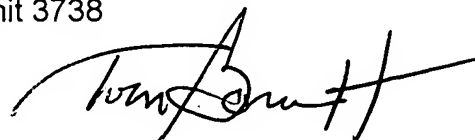
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached on Mon. -Fri. from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas C. Barrett
Examiner
Art Unit 3738

A handwritten signature in black ink, appearing to read 'Tom Barrett', with a stylized flourish at the end.

TOM BARRETT
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700